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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,276	04/05/2001	Garth S. Jones	00-721-US	6338
7590 Frederick H. Colen Reed Smith LLP P.O. Box 488 Pittsburgh, PA 15230-0488			EXAMINER KHARE, DEVESH	
			ART UNIT 1623	PAPER NUMBER

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/828,276

Applicant(s)

JONES ET AL.

Examiner

Devesh Khare

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,6-10 and 21-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,6-10 and 21-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's Amendment and remarks filed on 12/31/03 are acknowledged.

Claims 2, 3, 5, 11-20 have been cancelled. Claims 1,4, 6-10 and 21-30 are currently pending in this application.

35 U.S.C. 103(a) rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,4,6-10 and 21-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. (U.S.Patent 6,376,472) in view of Olsson et al. (U.S.Patent RE37,045 E) of record.

Claims 1,4,6-10 and 21-30 are drawn toward an adenosine 2',3'-O-isopropylidene analogue, wherein R₁ and R₂ are each an amine group or an alkylamine group; R₃, R₄ and R₅ are each a hydrogen or a halogen; and R₆ is an alkyl alcohol group or a carboxamido group, its pharmaceutical compositions and specifically the adenosine-5'-carboxamide derivatives, of claims 9 and 29, wherein R₆ is a N-alkylcarboxamido group.

Myers et al. teach a compound of the formula where the ribose ring of the adenosine is 2',3'-O-isopropylidene derivative (see claim 1). See column 7, lines 52-63, wherein formula I shows an adenosine nucleoside compound; wherein variables A and B are OR' and OR'' and together these variables represent the structure in column 8, lines 41-

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44 and the R' and R'' variables may be hydrogen or alkyl, column 8, lines 46-50; wherein the variable T is the alkyl alcohol group R_3O-CH_2 set forth in column 8, line 25; wherein R_6 is hydrogen and X-Y of the prior art is seen to be a nitrogen containing ring. Pharmaceutical compositions of the invention as claimed are rendered obvious by the disclosure in column 45, lines 26-42; wherein adenosine analogues as disclosed may be formulated into pharmaceutical compositions. While the Myers et al's. 2',3'-O-isopropylidene derivatives of adenosine are closely analogous to the applicant's compounds, Myers et al's. compounds differ from applicant's claimed compounds in that there is no disclosure of adenosine-5'-carboxamide derivatives. It is noted that Myers et al do not provide specific disclosures regarding the substitution of an isopropylidene ring with an amine group or an alkyl amine group.

Olsson et al. teach the 5'- carboxamido derivatives of 2',3'-O-isopropylidene - adenosine (abstract). Olsson et al. disclose the derivatives of 5'-carboxamidoadenosine compounds of General Formula 8, wherein the substituents of carboxamide group are lower alkyl, hydroxyl, lower alkoxy or halogen substituted straight chain lower alkyl (col. 7, lines 8-15).

Therefore, one of ordinary skill in the art would have found the applicants claimed 5'- carboxamido derivatives of 2',3'-O-isopropylidene -adenosine(N-substituted) derivatives and its pharmaceutical composition to have been obvious at the time the invention was made having the above cited references before him. Since Myers et al. disclose the adenosine-5'-(N-substituted) derivatives and Olsson et al. disclose the 5'-carboxamido derivatives of 2',3'-O-isopropylidene -adenosine, one skilled in the art

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would have a reasonable expectation for success in combining both references to obtain the adenosine-5'-carboxamide compounds, wherein the carbohydrate group is substituted with an isopropylidene ring, its pharmaceutical compositions and specifically the compounds of claims 9 and 29. The motivation for doing so is provided by Myers et al., which suggests the use of Adenosine-5'-(N-substituted)carboxamides and carboxylate esters and N1-oxides thereof for their coronary vasodilating activities (col. 7, lines 1-3).

Rejection Maintained

Rejection of claims 1, 4, 6-10 and 21-30 under 35 U.S.C. 103(a) is maintained.

Response to Arguments

Applicant's arguments filed on 12/31/2003, traversing the rejection of claims 1,4, 6-10 and 21-30 under 35 U.S.C 103(a) have been fully considered but they are not persuasive.

Applicants present the argument that "Myer et al. do not teach the presently-claimed limitation where R_1 and R_2 are an amine group or an alkyl amine group. The newly cited '045 patent does not cure this deficiency of Myers et al."

It is noted that Myer et al. teach the derivatives of adenosine having a 2',3'-O-isopropylidene group (see claim 1). Myer et al. does not teach the 5'-carboxamide derivatives of adenosine having a 2',3'-O-isopropylidene group. The '045 patent teaches the 5'- carboxamido derivatives of 2',3'-O-isopropylidene -adenosine (abstract).

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Applicant has not demonstrated any criticality or unexpected result, which stems from selection of the limitation where R_1 and R_2 are an amine group or an alkyl amine group (substitution on the 2',3'-O-isopropylidene group). Furthermore, Myer et al. discloses the prodrugs wherein the hydroxyl groups on the ribose can be protected by forming the 2',3'- isopropylidene derivatives (col. 21, lines 11-15 and col. 22, Reaction scheme E) and the '045 patent teaches the 5'- carboxamido derivatives of 2',3'-O-isopropylidene - adenosine, therefore the 2',3'-O-isopropylidene derivatives of adenosine and the 5'- carboxamide derivatives of adenosine having a 2',3'-O-isopropylidene group are within the teachings of Meyer and '045 patent.

2. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the


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Examiner should be directed to Devesh Khare whose telephone number is (571)272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at (571)272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,JD(3Y).
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May 20,2004



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600